UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,165	06/12/2000	PATRICK W. GRAY	27866/34810	7556

7590 12/03/2002

DAVID A GASS
MARSHALL O'TOOLE GERSTEIN MURRAY & BORUN
633 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, IL 60606-6402

EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	17

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,165	GRAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 26-37* is/are pending in the application.

4a) Of the above claim(s) *1-14,27-29 and 32-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-14, 26-37 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group VII, claims 26, 30-31 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that cited references in the previous Office Action do not teach the special technical feature of the claimed invention, the restriction requirement should be withdrawn, and the claims should be examined as a whole. This is not found persuasive because the claimed invention in group I read on a purified non-human vertebrate macrophage derived chemokine (MDC) polypeptide that are capable of inhibiting at least one biological activity of the MDC polypeptide.

2. Applicants' argument has been fully considered; however, it is not found persuasive because one of the cited references by Vicari et al. teach a novel cc chemokine, TECK, which is expressed by murin thymic dendritic cells and potentially involved in T cell development. The human MDC is also highly expresses in the thymus and dendritic cells, which is also suggests it has an additional function in T cell development as taught by Goldiska et al. (J. Exp. Med. 1997, Vol. 185, pp. 1595-1604, especially see the section of discussion on page 1601, 2nd paragraph through 4th paragraph). Therefore, comparing the similar expression patter and function, it is suggested that TECK is a counter part of human MDC in murine.

3. Therefore, according to the concept of PCT Rule 13.2, they lack the same or corresponding special technical features, which link all claimed invention together.

4. Furthermore, according to the concept under PCT Rule 13.1, claims in the present application did not related to a single general inventive concept. For example, the invention of group VII is drawn to a method for palliating an allergic reaction, whereas, the invention of group VIII is drawn to a method for treating platelet aggregation, and the invention of group IX is drawn to a method for treating lupus. The invention of group IV is drawn to a kit for assaying MDC polypeptide. They are all pantenable distinct each from other.

Priority

5. This application repeats a substantial portion of prior Application No. 08,939,107, filed on 09/26,1997, and adds and claims additional disclosure not presented in the prior application SN. 08,660,542, filed on 06/07/1996. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application 09/26/1997, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Information Disclosure Statement

6. The information disclosure statement filed 05/06/2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because some of the information disclosure statement fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Some of the listed references that do not have a copied or examiner cannot located the copied as indicated in the IDS have been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague and indefinite in that the metes and bounds of recited an amount effective" are not defined. Claim is interpreted in light of the specification; however, specification does not teach what is the amount effective is. Please clarify. This affects the dependent claims 30 and 31.

Claim 30, is vague and indefinite in that the metes and bounds of a fragment or analog of are not define. The claim is interpreted in light of the specification, however, the limitation in the

specification does not read into the claim. It Applicants with to claim a particular fragment or analog, please point out precise structure of the fragment or analog that is intended.

The claim 30 is also vague for recitation of a relative word "capable of", because the capability of a compound or composition to perform some function is merely a statement of a latent characteristic of said compound or composition and said language carries no patenable weight. Therefore, the claims are regarded as indefinite.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosure in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and gain in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors are analyzed according the situation of the present application.
1) & 2) State of art and unpredictability.

It is known in the art that Allergy is caused by the infiltration of eosinophils. MDC and TARC share same receptor CCR4. CCR4 is related to the allergy reaction; however, this receptor is not expressed in eosinophil. It has been reported that the chemotaxis of eosiphile induced by MDC is a CC chemokine receptor CCR3 and CCR4 independent as evidenced by Bocher et al. (J. Allergy Clin. Immunol. 1999, Vol. 103, pp. 527-532). The art at the time of application's

invention was nil, with no demonstrative unambiguous successes in treating allergic reaction in humans with MDC antagonist or TARC antagonist.

3) & 4) Number of working examples and amount of guidance.

Applicants only has a limited teaching that presents human MDC being able to induce eosinophile chemotaxis in vitro through a CCR4 independent manner. The monoclonal antibodies against human MDC, 252Y and 252Z inhibit CCR4 mediated cellular response to MDC in CCR4 transfected cell lines and block the antigen-induced asthma in an animal model.

However, Applicants does not teach that any or all MDC antagonist or TARC antagonist is able to inhibit any or all allergic reaction in vitro and in vivo.. The specification lack the evidence that TACR antagonist, any or all polypeptide fragment or analog of vertebrate MDC, such as murine MDC, Rat MDC and CCR4 receptor or fragment thereof of CCR4 is able to inhibit the allergic reaction. As MDC induced the eosinophil accumulation is a CCR4 or CCR3 independent, whether the use of CCR4 is able to block the MDC induced eosinophil accumulation is questionable and lacks supporting evidence.

5) Scope of the claims.

The scope of claims read broad with a method for treating allergic reaction by using any or all MDC antagonist or TARC antagonist.

6) & 7) Nature of invention and lever of the skill in the art.

The nature of the invention is related to use a molecular biology technique to searching large a mount of MDC antagonist and testing the possible biological antagonist effects both in vitro and in vivo. The level of the skill is high.

Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Wells et al. (WO 96/23068A1).

12. Wells et al. disclose a method for using a substance of CCR4, which has 100% homology to SEQ ID NO: 34 as it is claimed in the present application, to treat some allergic problem, such as asthma, food allergy, atopic dermatitis etc. (claim 1-5 and lines 3-11 on page 16. Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

Claim 31 is deemed free of prior art, given failure of the prior art to teach or reasonably suggest that use of anti-MDC antibodies for reducing the eosinophile related allergy reaction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

JAMES HOUSEL 12/2/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

November 25, 2002